

“replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). A device is placed in Class III based on the risk entailed in its use and the lack of available information ensuring that it can be safely sold without prior review for safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C).

Generally speaking, Class III medical devices are subject to a “rigorous regime of premarket approval” administered by the FDA. *Riegel*, 552 U.S. at 317. In certain defined situations, however, it is permissible to bring a Class III device to market without completing the full FDA approval process. Specifically, the MDA “grandfathered many [devices] that were already on the market,” allowing those devices to “remain on the market until the FDA promulgates, after notice and comment, a regulation requiring premarket approval.” *Id.* (citing 21 U.S.C. §§ 360c(f)(1), 360e(b)(1)). The MDA’s grandfathering provision applies not only to the specific devices that pre-dated the MDA, but also any “substantially equivalent” devices. *Id.*

If a company seeks to sell a Class III device as “substantially equivalent” to a grandfathered device, it must submit the device to an FDA review “known as the § 510(k) process, named after the statutory provision describing the review.” *Id.* Although the § 510(k) process does entail submitting the device to some degree of regulatory scrutiny, it is generally understood that a § 510(k) review, because it is focused only on substantial equivalence, will be less comprehensive and onerous than a premarket review for a non-grandfathered Class III device.

InMode is an Israeli medical device corporation. Invasix is a Canada-based Delaware corporation that allegedly “acts as the North American division” of InMode. (Docket No. 76-12 ¶¶ 6, 17.) InMode and Invasix sell a Class III medical device under the trade name “Fractora,” which, according to Jones, is “designed, manufactured and sold in North America by Invasix.” (*Id.* ¶ 1.) The Fractora device consists of a console and a handheld applicator, with a disposable tip, designed to deliver radiofrequency electrical current to human skin. (*Id.* ¶ 23.) The Fractora device

is used to “vaporize columns of skin,” which in turn “stimulates the body’s production of collagen” in order to “leave[] the skin looking and feeling smoother.” (*Id.* ¶ 24.) Invasix submitted a § 510(k) application for the Fractora device around late May of 2011, and it was ultimately approved as substantially equivalent to a grandfathered device. (*Id.* ¶ 21 & n.1)

According to Jones, however, the approval of the Fractora as a substantially equivalent device was the result, at least in part, of improper actions by the defendants during the device’s § 510(k) review. In particular, the defendants’ § 510(k) application described the intended application of the Fractora device in a manner that differed, in several key ways, from the uses for which the defendants ultimately marketed the device. (*Id.* ¶¶ 35–38.) As a result, Jones alleges, the defendants were able to take the least challenging available route to approved sales of a Class III device—intended exclusively for devices that had already been used for many years or slight variations thereon—only to then market the Fractora as a “revolution in medical devices” to be used in dangerous ways that the FDA never considered.² (*Id.* ¶ 22.)

Jones is an aesthetician who works in the office of Dr. Paulino E. Goco in Nashville. Jones had a Fractora procedure—in fact, her third Fractora procedure—performed on her face by one of Dr. Goco’s other aestheticians on November 15, 2017. Jones characterizes the procedure as “only to refresh her skin, which was virtually wrinkle-free and healthy-looking.” (*Id.* ¶ 52.) Earlier, Jones and other aestheticians from the office had met with Invasix representatives and an Invasix trainer. These representatives assured Jones and other aestheticians that the Fractora procedure “was an extremely safe, painless and non-invasive alternative to face lift and [laser] procedures.” (*Id.* ¶ 53.) The representatives told Jones that “the procedure was risk-free and would require little

² Jones alleges several additional types of wrongdoing related to the promotion of the Fractora device. The details of those allegations are immaterial to the issues presented by the pending motions .

downtime.” (*Id.*) They also recommended that aestheticians perform the procedures, despite the fact that Fractora had only been approved for use by physicians. (*Id.* ¶ 54.)

Neither of the Fractora procedures that Jones underwent prior to November 15, 2017, had resulted in any unexpected ill effects. For the third procedure, however, the aesthetician slightly changed the treatment parameters by using a different tip, the “60 pin tip.” (*Id.* ¶¶ 55–56.) Jones and the other aesthetician, Tricia King, selected that tip based on training they had received from Invasix and an Invasix-published Quick Reference Guide. (*Id.* ¶ 57.) The procedure “left Mia’s face extremely red and a little swollen even after using a cooling device,” after which she began scabbing. Due to the “condition of her face,” she took three days off of work. (*Id.* ¶ 56.)

According to her proposed Second Amended Complaint, Jones “first became concerned her injury was beyond that intended by the procedure when her condition worsened over the next few months.” (*Id.* ¶ 63.) On January 8, 2018, she saw a physician, Dr. Natalie Curcio, with whom she discussed the situation. According to Dr. Curcio’s notes, she suggested that Jones not undergo any new procedure to attempt to address the results of the treatment and instead wait, for the time being, to see how she continued to heal. (*Id.*) In April of 2018, Jones saw another physician, Dr. William Stebbins, who told her that “it would be at least another six months before her skin had fully healed and an evaluation of potential unintended and persistent injury completed.” (*Id.*)

In her original Complaint, Jones described an email exchange between her and Dr. Goco on January 17 and 22, 2018, regarding what had happened during the Fractora procedure. In particular, the email discussed a conversation that Jones had had with the Invasix trainer, Wanda Cummings. Dr. Goco asked, “Did she give [you] any idea why that happened to you???” Jones stated that Cummings had told her that she should not have used a particular tip on her face. Jones complained, however, that a chart in the Invasix guide had “said it was ok.” (Docket No. 1 ¶ 105.) According to Jones’ Second Amended Complaint, however, “Cummings never told [her] that her

experience was outside the expected results for the procedure or characterized Mia's experience as an injury rather than part of the varying and normal responses to the treatment." (Docket No. 76-12 ¶ 61 (emphasis omitted).)

On January 23, 2019, several individuals, including Jones, entered into a Tolling Agreement with Invasix "and any other related and affiliated corporations and businesses" covering potential claims related to the Fractora. (Docket No. 76-4 at 1.) According to the Tolling Agreement, the parties were pursuing non-judicial resolution of the individuals' potential claims. In furtherance of settlement discussions, they agreed to a "Tolling Period" beginning on the effective date of the agreement. (*Id.* at 1–2.) The parties agreed that any statute of limitations, laches, waiver, or timely action defenses would "be tolled during the Tolling Period," but that the agreement would "have no effect on any Timing Defenses that may be available to Defendants, known or unknown, prior to the Effective Date." (*Id.* at 2.) The Tolling Agreement was ultimately extended through April 18, 2019. (*Id.* at 8.)

Jones did not settle her claims, and, on April 17, 2019, she, along with two co-plaintiffs, Heather Wanke and Janice Newman, filed their original Complaint in the Central District of California. (Docket No. 1.) That Complaint named only Invasix as a defendant. (*Id.* at 1.) On May 15, 2019, the plaintiffs filed a Waiver of Service that had been signed by counsel for Invasix on May 3, 2019. (Docket No. 17.) On June 28, 2019, Invasix filed a Motion to Sever and Transfer Plaintiffs' Claims. (Docket No. 20.) Invasix noted that Jones and Hanke were Tennessee residents, who had procedures performed on them in Tennessee, while Newman was a New York resident whose Fractora procedure was performed in New York. Moreover, Invasix argued, each plaintiff's claims involved unique questions regarding each patient's treatment, rendering joinder inappropriate. (Docket No. 20-1 at 9.) The plaintiffs opposed the motion, arguing that their claims were based on the same course of wrongdoing by Invasix and that the Central District of California

was the most convenient forum for key non-party witnesses. (Docket No. 28 at 3, 14.) The court granted both of Invasix's requests, severing the plaintiffs' cases and transferring each case to the plaintiff's home district—that being, in Jones' case, the Middle District of Tennessee. (Docket No. 36.)

On October 22, 2019, Jones filed an Amended Complaint adding InMode as a defendant. (Docket No. 58 at 1.) The Amended Complaint includes seven causes of action. The First Cause of Action is for breach of express warranty. (*Id.* ¶¶ 69–74.) The Second Cause of Action is for breach of implied warranty. (*Id.* ¶¶ 75–79.) The Third Cause of Action is for violation of the California Unfair Competition Statute (“CUCS”), Cal. Bus. & Prof. Code § 17200 *et seq.*³ (*Id.* ¶¶ 80–87.) The Fourth Cause of Action is for violation of the California False Advertising Law (“CFAL”), Cal. Bus. & Prof. Code § 17500 *et seq.* (*Id.* ¶¶ 88–94.) The Fifth Cause of Action is for common law fraud. (*Id.* ¶¶ 95–97.) The Sixth Cause of Action is for negligence, negligence *per se*, and gross negligence. (*Id.* ¶¶ 98–105.) The Seventh Cause of Action is for strict liability. (*Id.* ¶¶ 106–10.)

On November 6, 2019, Jones filed a Notice with the court requesting the issuance of a summons to InMode. (Docket No. 60.) The proposed Summons identified InMode's address as a particular post office box in Israel. (Docket No. 60-1 at 1.) A summons was issued shortly thereafter. (Docket No. 61.) A receipt provided to InMode by Jones shows that she sent the Summons to InMode's believed address by registered mail. (Docket No. 70-1 at 3.) According to an Affidavit by InMode's counsel, InMode did receive the Summons, likely through the mail office of its Israeli facilities. (Docket No. 70-3 ¶¶ 5–10.)

³ Jones has alleged that CUCS applies because the defendants' “wrongful conduct . . . emanate[d] in California.” (*Id.* ¶ 85.)

The parties agreed to extend InMode's time to file a responsive pleading until February 27, 2020, and the court entered an Order to that effect. (Docket No. 66.) On February 27, 2020, Invasix and InMode filed separate Motions to Dismiss. (Docket Nos. 67 & 69.) Invasix argues that all of Jones' claims are time-barred. (Docket No. 67 at 1.) InMode, which has, so far, only specially appeared in this court, argues both that the claims are time-barred and that InMode has not properly been served. InMode asks the court to dismiss the claims or, in the alternative, to quash the service of the summons. (Docket No. 69 at 1.)

On March 10, 2020, Jones filed an Affidavit of Service regarding InMode. (Docket No. 72.) She explained that she had not yet received a return receipt confirming the delivery of the Summons. (*Id.* at 1.) She had therefore tried, in January, to send the Summons again, but she did not receive a return receipt for that delivery either. (*Id.*) The same day, Jones filed a Motion for Leave to File a Second Amended Complaint. (Docket No. 73)

The proposed Second Amended Complaint includes several new paragraphs under the heading "Facts Concerning Statute of Limitations," the first of which explains as follows:

The Fractora procedure involves the intentional destruction of tissue so that new collagen will form, tightening and otherwise resurfacing the skin. All Fractora patients experience an injury and [patients] heal at different rates. The condition of Plaintiff's skin worsened over time after the procedure. Plaintiff only suspected she might have suffered an unintended injury with long term changes in her skin in early 2018[.] Subsequently, two physicians told Plaintiff she should not be alarmed, that she could expect her skin to continue healing for up to a year and that it would be impossible to determine whether she had any actual injury (as opposed to the intentional tissue damage and expected healing time for the Fractora) for at least a year after the procedure. A year's time confirmed that [Jones'] procedure caused an injury to her skin beyond that which is intended and she has suffered a cognizable injury caused by Defendants—permanent scarring, changes in skin texture and color and loss of volume. Thus, based on the advice of multiple [doctors], Plaintiff did not and could not through exercise of reasonable diligence known she suffered a cognizable injury as a result of the Defendant's wrongful conduct until November 15, 2018.

(Docket No. 76-12 ¶ 7.)

II. LEGAL STANDARD

A. Motion to Dismiss Based on Insufficient Service of Process

Rule 12(b)(5) authorizes the court to dismiss a complaint for insufficiency of service of process. *Metro. Alloys Corp. v. State Metals Indus., Inc.*, 416 F. Supp. 2d 561, 563 (E.D. Mich. 2006). The party on whose behalf service of process was made has the burden of establishing its validity. *Shires v. Magnavox Co.*, 74 F.R.D. 373, 377 (E.D. Tenn. 1977). In deciding a motion to dismiss under Rule 12(b)(5), the court may refer to record evidence in determining the sufficiency of service. *Thompson v. Kerr*, 555 F. Supp. 1090, 1093 (S.D. Ohio 1982). The court also may consider facts attested to in uncontroverted affidavits in ruling on a Rule 12(b)(5) motion to dismiss. *Shires*, 74 F.R.D. at 376–77.

B. Motion to Amend

Rule 15(a)(2) of the Federal Rules of Civil Procedure states that leave to amend should be freely given “when justice so requires.” In deciding whether to grant a motion to amend, courts should consider undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment. *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005). “Amendment of a complaint is futile when the proposed amendment would not permit the complaint to survive a motion to dismiss.” *Miller v. Calhoun Cty.*, 408 F.3d 803, 817 (6th Cir. 2005) (citing *Neighborhood Dev. Corp. v. Advisory Council on Historic Pres.*, 632 F.2d 21, 23 (6th Cir. 1980)).

III. ANALYSIS

A. InMode’s Motion to Dismiss for Insufficient Service

InMode argues that Jones has failed to properly serve her Complaint and Summons on it and that her claims should therefore be dismissed or, in the alternative, that the court should quash

the service. Jones responds that her mailing of the Summons and Complaint by registered mail was a permissible form of serving a complaint filed in U.S. District Court on an Israeli business entity, pursuant to the relevant governing laws.

The United States and Israel are both parties to the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil and Commercial Matters, Nov. 15, 1965 (“Hague Service Convention”), 20 U.S.T. 361, T.I.A.S. No. 6638, a “multilateral treaty [intended] to simplify, standardize, and generally improve the process of serving documents abroad.” *Water Splash, Inc. v. Menon*, 137 S. Ct. 1504, 1507 (2017). “To that end, the Hague Service Convention specifies certain approved methods of service and ‘pre-empts inconsistent methods of service’ wherever it applies.” *Id.* (quoting *Volkswagenwerk Aktiengesellschaft v. Schlunk*, 486 U.S. 694, 699 (1988)). At the heart of the Hague Service Convention structure is the requirement that “each state . . . establish a central authority to receive requests for service of documents from other countries.” *Schlunk*, 486 U.S. at 698–99 (citing 20 U.S.T. 362, T.I.A.S. 6638, Art. 2). Indeed, Jones’ attorney’s travails in attempting to navigate the international mail system for this case provide an example of the benefits of the “central authority” system. Each nation’s central authority provides a way to effect service without having to master the sometimes opaque logistics of getting a document into the hands of a private party in a foreign country (and obtaining documentation that you did so). Jones did not comply with the standard Hague Convention process, choosing instead to mail the Summons directly to InMode herself. InMode argues that, because she did so, her claims should be dismissed.

Article 10(a) of the Hague Service Convention, however, states that, “[p]rovided the State of destination does not object, the present Convention shall not interfere with . . . the freedom to

send judicial documents, by postal channels, directly to persons abroad”⁴ InMode concedes that Israel does not object to Article 10(a). InMode argues, however, that Article 10(a) should be read to address only “send[ing]” documents but not *serving* documents. In other words, InMode argues that the court should read Article 10(a) as merely preserving the right to rely on the mails for the transmission of all documents other than the select few for which formal service of process is required.

The U.S. Supreme Court, however, considered that argument at length in *Water Splash, Inc. v. Menon*, only to reject such a reading as “atextual” and “structurally implausible,” with “no sustained argument in support of it.” 137 S. Ct. at 1510. InMode, fails to address *Water Splash*, relying, instead, on Tennessee cases that pre-date the U.S. Supreme Court’s decision. The meaning of a treaty in domestic courts, however, is an issue of federal law, on which the U.S. Supreme Court has the final say. *See, e.g., Sanchez-Llamas v. Oregon*, 548 U.S. 331, 346–47 (2006) (“[W]here a treaty provides for a particular judicial remedy, there is no issue of intruding on the constitutional prerogatives of the States or the other federal branches. Courts must apply the remedy as a requirement of federal law.”); *see also* U.S. Const. art. VI, cl. 2 (“[A]ll Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

Regardless of whether InMode has adequately addressed *Water Splash*, however, Jones had an obligation to serve her Summons and Amended Complaint in accordance with the relevant law, as interpreted by that case. The Supreme Court, in *Water Splash*, set forth the rule for service by mail under the Hague Service Convention as follows:

⁴ The text and supporting documentation for the Hague Service Convention can be found at <https://www.hcch.net/en/instruments/conventions/full-text/?cid=17>.

In short, the traditional tools of treaty interpretation unmistakably demonstrate that Article 10(a) encompasses service by mail. To be clear, this does not mean that the Convention affirmatively authorizes service by mail. Article 10(a) simply provides that, as long as the receiving state does not object, the Convention does not “interfere with . . . the freedom” to serve documents through postal channels. In other words, in cases governed by the Hague Service Convention, service by mail is permissible if two conditions are met: first, the receiving state has not objected to service by mail; and second, service by mail is authorized under otherwise-applicable law.

Water Splash, 137 S. Ct. at 1513.

With regard to whether Israel objects to service by mail, InMode—despite ultimately conceding that it does not—seeks to rely on Israel’s Declaration under the Hague Service Convention, which states:

The State of Israel, in its quality as State of destination, will, in what concerns Article 10, paragraphs b) and c), of the Convention, effect the service of judicial documents only through the Directorate of Courts, and only where an application for such service emanates from a judicial authority or from the diplomatic or consular representation of a Contracting State

InMode argues that the Declaration, by referring to service “only through” Israel’s central authority, suggests that Israel does not consider Article 10(a) to create an exception for service by mail. That language, however, is expressly directed at parts of the Convention other than Article 10(a). Israel’s lack of an objection to Article 10(a) in particular is the end of the inquiry with regard to Israeli law, at least at this step of the analysis.

Service by mail was permissible under *Water Splash*, therefore, to the extent authorized by U.S. law. Service on foreign business entities⁵ in federal courts is governed by Rule 4(h)(2) of the Rules of Civil Procedure, which permits service “in any manner prescribed by Rule 4(f) for serving an individual, except personal delivery under (f)(2)(C)(i).” Rule 4(f) permits service as follows:

⁵ Technically, the method of service under Rule 4 depends on whether the service itself is performed abroad, not on the nationality of the business entity. Fed. R. Civ. P. 4(h)(2). For ease of reading, however, the court will refer to the service on a business entity outside the United States as service on a foreign business entity.

(1) by any internationally agreed means of service that is reasonably calculated to give notice, such as those authorized by the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents;

(2) if there is no internationally agreed means, or if an international agreement allows but does not specify other means, by a method that is reasonably calculated to give notice:

(A) as prescribed by the foreign country's law for service in that country in an action in its courts of general jurisdiction'

(B) as the foreign authority directs in response to a letter rogatory or letter of request; or

(C) unless prohibited by the foreign country's law, by: . . .

(ii) using any form of mail that the clerk addresses and sends to the individual and that requires a signed receipt; or

(3) by other means not prohibited by international agreement, as the court orders.

Fed. R. Civ. P. 4(f).

Rule 4(f)(3) is inapplicable here because Jones did not receive prior authorization from the court to effect service by mail. *See Lexmark Int'l, Inc. v. Ink Techs. Printer Supplies, LLC*, 291 F.R.D. 172, 174 (S.D. Ohio 2013) (stating that service under Rule 4(f)(3) "must be directed by the court"). Jones cannot rely on Rule 4(f)(2)—which covers situations where the relevant treaty "allows but does not specify" a particular method of service—because her mailing was not addressed and sent by the clerk of this court. *See Wright & Miller*, 4B Fed. Prac. & Proc. Civ. § 1134 (4th ed.) ("The rule requires that the mail must be addressed and sent to the party to be served by the clerk of the court. Service by mail is improper, therefore, if addressed and dispatched by the plaintiff."). Jones, therefore, must rely on Rule 4(f)(1), which permits service "by any internationally agreed means of service that is reasonably calculated to give notice, such as those *authorized by the*" Hague Service Convention. (Emphasis added.)

As the Supreme Court expressly stated in *Water Splash*, however, the Convention does not “affirmatively authorize[] service by mail.” 137 S. Ct. at 1513. It merely permits service by mail as long as the country of service does not object and “service by mail is authorized under otherwise-applicable law.” *Id.* The only “otherwise-applicable” law for serving a business entity in Israel under the Federal Rules, however, is service by Rule 4(f)(2) or (3), which, as the court has already explained, would not suffice to render Jones’ service proper in this case. *See* 1 Moore’s Federal Practice–Civil § 4.52[2][d] (2020) (explaining that the manner for sending service by mail under the Federal Rules pursuant to *Water Splash*’s “otherwise-applicable law” rule is through Rule 4(f)(2)(C)(ii), requiring mail sent by the clerk).

Jones argues that the court should hold that service by mail from the plaintiff is permissible here because it is an authorized form of service under Rule 4.04(10) of the Tennessee Rules of Civil Procedure. Jones, however, does not explain why the Tennessee Rules would govern in this instance. Admittedly, state service rules play a role in most of this court’s civil cases. That, however, is because most of this court’s cases involve domestic service of process, which may be performed “following state law for serving a summons in an action brought in courts of general jurisdiction in the state where the district court is located or where service is made.” Fed. R. Civ. P. 4(e)(1), (h)(1)(A). No similar express incorporation of state law exists for foreign service of process. *See* Wright & Miller, 4B Fed. Prac. & Proc. Civ. § 1114 (4th ed.) (stating that the Rule 4(e) incorporation of state rule for serving a summons “applies to service ‘in a judicial district of the United States’”) (quoting Fed. R. Civ. P. 4(e)). Moreover, even if Tennessee’s Rules did apply, Rule 4.04 is expressly limited only to service within the state. Service on foreign corporations is governed by Rule 4A of the Tennessee Rules of Civil Procedure, which largely mirrors Rule 4(f) and (h) of the Federal Rules.

Jones' service on InMode was, therefore, improper. Usually, "[i]f a defendant is not served within 90 days after the complaint is filed, the court—on motion or on its own after notice to the plaintiff—must dismiss the action without prejudice against that defendant or order that service be made within a specified time." Fed. R. Civ. P. 4(m). That rule, however, "does not apply to service in a foreign country under Rule 4(f), 4(h)(2), or 4(j)(1)." *Id.* Moreover, even where dismissal is permitted, "[t]he federal courts have broad discretion to dismiss the action or to retain the case but quash the service that has been made on the defendant. . . . When process is quashed, only the service need be repeated." Wright & Miller, 5B Fed. Prac. & Proc. Civ. § 1354 (3d ed.). There is no evidence that InMode was prejudiced by the improper service, and the court sees no reason why the interests of justice would be served by dismissal. The court, accordingly, will, relying on its power to authorize the method of service under Rule 4(f)(3), order Jones to serve the Summons as soon as reasonably practicable by any method not forbidden by applicable international agreements, including certified mail.

B. Motion to Amend

Although InMode has not yet been properly served in this matter, it did make a special appearance for the purpose of seeking dismissal of Jones' claims on timeliness grounds. Indeed, InMode asked the court to reach the service of process issue only if it did not conclude that the claims were time-barred. (Docket No. 82 at 1 ("This court should not even need to address the issue of whether InMode was properly served since plaintiff's claims against InMode are time-barred.)) The court, therefore, will treat InMode as having consented to the court's exercise of jurisdiction for the limited purpose of resolving the issues raised by the pending motions. Invasix has sought dismissal for untimeliness as well. Jones opposes those motions but has also sought leave to amend her Complaint to plead certain facts relevant to the application of the statute of limitations.

A number of factors guide the court's decision under Rule 15(a)(2), but one factor, as a practical matter, most often takes the central place in the court's analysis of a request for leave to amend a complaint: whether the amendment would be futile. The policy of liberally allowing amendments in the interests of justice reflects the principle that, "[i]f the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Accordingly, as long as there was no undue delay, abuse of the amendment process, or bad faith, and as long as the opposing party will not be too severely prejudiced, whether an amendment will be allowed typically hinges on whether the amendment will actually solve the substantive problems it is intended to solve. By the same token, however, if an amendment would be futile, there is no benefit from allowing the amendment to go forward, even if other factors would support allowing the amendment. The court, therefore, will first consider whether Jones' amendments, which primarily seek to establish the potential timeliness of her claims, would be futile, and then, if the court finds that they would not be, the court will turn to the remaining considerations.

1. Waiver of Statute of Limitations Defense by Invasix

As a threshold matter, Jones argues that, by failing to file a timely answer, Invasix has waived its statute of limitations defense by failing to file a timely responsive pleading. A domestic defendant who waives service of process is required to respond to the complaint "within 60 days after the request for a waiver was sent." Fed. R. Civ. P. 12(a)(1)(A)(ii). The defendant's answer must "affirmatively state any avoidance or affirmative defense," including statute of limitations defenses. Fed. R. Civ. P. 8(c)(1). It is undisputed that Invasix failed to file an answer preserving the statute of limitations defense—or, indeed, any answer—during the applicable 60-day period. Invasix did, however—after that 60-day period had elapsed—file a Rule 12(b)(6) motion raising the issue.

Jones does not dispute that Invasix could have preserved its affirmative defense by way of a motion to dismiss—if that motion to dismiss had been filed within the period for filing an answer. She argues, however, that Invasix’s failure to file the motion within the period for filing an answer should have the same consequences as failing to file an answer. As Jones admits, there is no express requirement, under Rule 12, that a Rule 12(b) motion must be filed within the 60-day answer period. Some courts, however, have inferred, from the requirement that a Rule 12(b) motion must be filed *before* the answer, that a defendant cannot extend the time for filing a Rule 12(b) motion simply by missing the deadline for an answer without receiving an extension. *See Gillo v. Gary Cmty. Sch. Corp.*, No. 2:14-CV-99-JVB-JEM, 2014 WL 3767680, at *2 (N.D. Ind. July 31, 2014) (collecting cases). Jones, however, admits that that issue presents an unsettled question, and she identifies no Sixth Circuit Court of Appeals case endorsing her position.

Moreover, even if the court accepted Jones’ reading of the sixty-day requirement, caselaw in the circuit is clear that the rule for raising affirmative defenses can and should be applied flexibly, as long as the plaintiff is not unduly prejudiced. “Under Federal Rule of Civil Procedure 8(c), ‘a party must affirmatively state any avoidance or affirmative defense’ in the answer, Fed. R. Civ. P. 8(c), but under common law, a ‘[f]ailure to raise an affirmative defense by responsive pleading does not always result in waiver.’” *Shelbyville Hosp. Corp. v. Mosley*, No. 4:13-CV-88, 2017 WL 5586729, at *14 (E.D. Tenn. Nov. 20, 2017) (quoting *Smith v. Sushka*, 117 F.3d 965, 969 (6th Cir. 1997)). “Where the matter is raised in the trial court in a manner that does not result in unfair surprise[,], technical failure to comply precisely with Rule 8(c) is not fatal.” *Moore, Owen, Thomas & Co. v. Coffey*, 992 F.2d 1439, 1445 (6th Cir. 1993) (quoting *Allied Chem. Corp. v. Mackay*, 695 F.2d 854, 856 (5th Cir. 1983); *see also In re Cipriano*, No. 14-14826, 2015 WL 3441212, at *8 (E.D. Mich. May 28, 2015) (noting that statute of limitations defense that was apparent on the face of the complaint is “not waived simply because it was raised in a motion to

dismiss rather than in the answer”) (quoting *Pierce v. Oakland Cty.*, 652 F.2d 671, 672 (6th Cir. 1981)); *Peacock v. Equifax, Inc.*, No. 3:13-CV-651-PLR-HBG, 2015 WL 1457996, at *1 (E.D. Tenn. Mar. 30, 2015) (applying rule that, where no prejudice occurs and statute of limitations defense is raised by motion, the court may hold that the defense was not waived by failure to include it in an earlier responsive pleading). Because there has been no prejudice and because Invasix raised the statute of limitations prior to filing any Answer, the court will not treat that defense as waived.

2. Accrual of Claims Under the Discovery Rule

The parties appear to agree that Tennessee’s one-year statute of limitations governing causes of action based on personal injury, Tenn. Code Ann. § 28-3-104(a)(1)(A), applies to all of Jones’ claims.⁶ The defendants argue that Jones’ claims are time-barred because she filed them well over a year after her immediately negative response to her third Fractura procedure. They argue, moreover, that the Tolling Agreement cannot rescue her claims because, on its face, it explicitly disavows any agreement by the parties to affect any time-based defenses that were already available before the agreement went into an effect, and the agreement was made more than a year after Jones’ claims accrued. Jones, relying in part on the facts that she wishes to allege in her proposed Second Amended Complaint, argues that a question of fact exists with regard to when she reasonably should have known about her injuries and that, therefore, her claims should not be dismissed.

⁶ Neither party suggests that California law of timeliness or accrual should govern any aspect of this case, despite the fact that at least two of the counts are based on California substantive law. The question of how to apply causes of action across state lines has a complicated and at times challenging history. *See McCann v. Foster Wheeler LLC*, 225 P.3d 516, 525 (Cal. 2010) (discussing application of forum state causes of action under California law); *SunTrust Bank v. Ritter*, No. E2017-01045-COA-R3-CV, 2018 WL 674000, at *4 (Tenn. Ct. App. Feb. 1, 2018) (discussing same issues in Tennessee). Because neither party suggests that any statute of limitations other than Tennessee’s one-year limit should apply here, the court will treat the issue as conceded for the purposes of the pending motions.

The general rule is that “[s]tatute-of-limitations defenses are [more] properly raised in Rule 56 motions [for summary judgment], rather than Rule 12(b)(6) . . . motions, because ‘[a] plaintiff generally need not plead the lack of affirmative defenses to state a valid claim.’” *Munson Hardisty, LLC v. Legacy Pointe Apartments, LLC*, 359 F. Supp. 3d 546, 567 (E.D. Tenn. 2019) (quoting *Paulin v. Kroger Ltd. P’ship I*, No. 3:14-cv-669, 2015 WL 1298583, at *4 (W.D. Ky. Mar. 23, 2015)). However, if it is “‘apparent from the face of the complaint that the time limit for bringing the claim[s] has passed,’” then the plaintiff, if she wishes to avoid dismissal, has an “obligation to plead facts in avoidance of the statute of limitations defense.” *Bishop v. Lucent Techs., Inc.*, 520 F.3d 516, 520 (6th Cir. 2008) (quoting *Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 744 (6th Cir. 1992)). When “the allegations in the complaint affirmatively show that a claim is time-barred,” then “dismissing the claim under Rule 12(b)(6) is appropriate.” *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012).

For most ordinary causes of action, Tennessee courts apply the discovery rule to determine when a cause of action accrues. Under this rule, a cause of action accrues “when the plaintiff knows or in the exercise of reasonable care and diligence should know that an injury has been sustained as a result of wrongful or tortious conduct by the defendant.” *John Kohl & Co. v. Dearborn & Ewing*, 977 S.W.2d 528, 532 (Tenn. 1998) (citations omitted). In other words, the plaintiff must have suffered “legally cognizable damage—an actual injury,” and she “must have known or in the exercise of reasonable diligence should have known that this injury was caused by the defendant’s wrongful or negligent conduct.” *Id.* (citation omitted).

As the Tennessee Supreme Court has explained:

An actual injury occurs when there is the loss of a legal right, remedy or interest, or the imposition of a liability. An actual injury may also take the form of the plaintiff being forced to take some action or otherwise suffer some actual inconvenience, such as incurring an expense, as a result of the defendant’s negligent

or wrongful act However, the injury element is not met if it . . . amounts to a mere possibility.

Id. at 532 (citations omitted). Under the discovery rule, the statute of limitations begins to run, at the latest, when the plaintiff becomes aware that such an injury has been done to her. As the Tennessee Supreme Court explained, however, “[u]nder the theory of constructive knowledge, . . . the statute may begin to run at an earlier date—whenever the plaintiff becomes aware or reasonably should have become aware of facts sufficient to put a reasonable person on notice that an injury has been sustained as a result of the defendant’s negligent or wrongful conduct.” *Id.*

The plaintiff’s knowledge or constructive knowledge, moreover, need not entail a complete understanding of the severity or legal significance of the situation:

[T]here is no requirement that the plaintiff actually know the specific type of legal claim he or she has, or that the injury constituted a breach of the appropriate legal standard. Rather, the plaintiff is deemed to have discovered the right of action if he is aware of facts sufficient to put a reasonable person on notice that he has suffered an injury *as a result of wrongful conduct*.

Id. at 533 (emphasis added). Accordingly, in this case, it is immaterial when Jones knew or should have known how severe her injuries were or that the defendants violated any particular legal prohibition; what matters is when she knew or should have known that some wrongful injury had occurred.

Applying the discovery rule to an injury caused by a medical procedure or treatment is often difficult, because medical intervention can involve significant pain and suffering even when no wrongfulness occurs. *See, e.g., Sherrill v. Souder*, 325 S.W.3d 584, 594 (Tenn. 2010) (applying discovery rule to medication side effects); *Shadrick v. Coker*, 963 S.W.2d 726, 737 (Tenn. 1998) (applying discovery rule to effects of surgical screws); *Stanbury v. Bacardi*, 953 S.W.2d 671, 677 (Tenn. 1997) (applying discovery rule to results of foot surgery); *see also Cates v. Stryker Corp.*, No. 3:10-CV-546, 2012 WL 256199, at *3 (E.D. Tenn. Jan. 27, 2012) (applying discovery rule to

effects of implanted pain pump). As Jones points out, the very premise of her Fractora procedure was, in a sense, to injure her—to inflict controlled, planned damage to her tissue in order to cause a particular desired biological result. Accordingly, the mere fact that she, for example, took on a wounded appearance in the days following the procedure is not enough to allow the court to assume, for Rule 12(b)(6) purposes, that her claims accrued at that time. At some point, of course, her reaction to the procedure put her at least on inquiry notice of her claims, even if she did not yet know the extent of her injury or what precisely had been done wrong. However, “whether the plaintiff exercised reasonable care and diligence in discovering the injury or wrong is usually a question of fact for the jury to determine.” *Shadrick*, 963 S.W.2d at 737 (quoting *Wyatt v. A-Best, Co.*, 910 S.W.2d 851, 854 (Tenn. 1995)).

As an aesthetician who had received Fractora training and had access to Invasix personnel, Jones was in a significantly better position to understand what had happened to her than an ordinary patient would have been. Her own admissions, moreover, establish, at the very least, that, more than one year before she entered into the Tolling Agreement, she (1) was unhappy with how she had responded to the procedure and (2) had been told, by Invasix itself, that the way the Fractora device had been used on her had been inadvisable—despite having been done according to Invasix’s own guide. Jones may not have known, at the time, the extent or permanence of her injuries, but the discovery rule does not require her to. As long as she was or should have been aware that she had been injured—even temporarily—as the result of wrongful conduct, her claim could accrue.

The proposed Second Amended Complaint seeks to bolster her argument that there was still uncertainty about her injury until as much as a year after the procedure. Even the newly-alleged facts, frankly, leave significant room for doubt with regard to whether her claims were timely filed. The bar for granting a Rule 12(b)(6) motion based on a time-based affirmative

defense, however, is high; it must be apparent and beyond reasonable dispute, from the face of the complaint, that the plaintiff's claims were untimely in order to warrant dismissal. Even with the amended language, this case comes close to being one in which the court could take the unusual step of dismissing the claims rather than waiting for timeliness to be litigated on a summary judgment motion or at trial. Nevertheless, there is still some room for dispute. Even if one assumes that Jones knew, more than a year before her tolling agreement, that Invasix no longer recommended using the tip that had been used on her for facial procedures, that does not mean that she knew that the original advice in the guide had been wrongful, as opposed to merely superseded. Moreover, even if she knew that her reaction to the procedure had been far worse than most, she did not necessarily know that her bad reaction was something other than simply her having had the bad luck to fall on the far negative end of the spectrum of ordinary responses to an appropriately performed procedure. Jones now claims that she reasonably believed, based on representations to her by medical professionals, that she was merely having a difficult healing period. Based solely on the face of the proposed Second Amended Complaint, there is a possibility that Jones' claims did not accrue until as much as a year after her procedure—that is, on November 15, 2018.⁷

Applying the November 15, 2018 accrual date to Jones' claims would allow her until November 15, 2019 to file her claims. She filed her original Complaint naming Invasix on April 17, 2019, and she named InMode as a defendant on October 22, 2019. Allowing the amendment would not, therefore, be futile, at least with regard to overcoming motions to dismiss.

3. Weighing of Amendment Factors

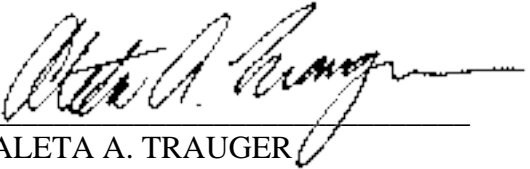
⁷ The court notes that, although motions for summary judgment are most typically filed following the completion of discovery, the defendants could seek summary judgment on this issue earlier if they feel the information already available to them is sufficient to resolve the matter.

Most of the other factors relevant to a motion for leave to amend support allowing Jones' amendment. It is still relatively early in the litigation, and Jones has not abused the amendment process in the past. There is no basis for concluding that the defendants would be unduly prejudiced by the amendment, as opposed to merely facing the ordinary costs of having a motion to dismiss met with an amended complaint rather than simply a brief in opposition. The issue of bad faith does raise some concerns, particularly given information that the defendants have provided—such as the timing of Jones' seeking out an attorney—that could be seen as suggesting that the claims in Jones' amendment may be less than true. At this stage, however, the court's misgivings are not great enough to bar an otherwise appropriate amendment. The court, accordingly, will grant Jones leave to amend.

IV. CONCLUSION

For the foregoing reasons, Invasix's Motion to Dismiss (Docket No. 67) will be denied as moot, InMode's Motion to Dismiss (Docket No. 69) will be granted in part and denied in part as moot, and Jones' Motion for Leave to File a Second Amended Complaint (Docket No. 73) will be granted. The court will prospectively authorize service on InMode by any method not forbidden by relevant international agreements.

An appropriate order will enter.



ALETA A. TRAUGER
United States District Judge